DIAZYME

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K050178

Summary

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Date the summary was prepared: December 25, 2004

Name of the device: HbA1C Enzymatic Assay
Trade Name: HbA1C Enzymatic Assay
Common/Usual Name: Enzymatic Assay, HbA1C
Classification Name: Glycosylated Hemoglobin Assay (Per 21CFR section 864.7470)
Device Class: II

Predicate Device:

The legally marketed device to which we are claiming equivalence [807.92(a)(3)]: G7 Automated HPLC Analyzer: HbA1c Variant Analysis Mode (K011434) manufactured by Tosoh Medics, Inc., San Francisco, CA, 94080.

Description of the device

The Diazyme's HbA1C assay kit is a clinical test kit, intended for quantitative determination of hemoglobin A1C in blood by an enzymatic method, to monitor long-term glucose control in individuals with diabetes mellitus.

The Diazyme's HbA1C assay kit is comprised of a Reagent 1, Reagent 2, Lysis Buffer, THb Reagent, and calibrators.

Measurement of hemoglobin A1C is determined enzymaticly by subjecting lysed whole blood samples to extensive protease digestion. This process releases amino acids including glycated valines from the hemoglobin beta chains. Glycated valines then serve as a substrate for fructosyl valine oxidase (FVO) enzyme which specifically cleaves N-terminal valines and produces hydrogen peroxide. The hydrogen peroxide is measured using a peroxidase catalyzed reaction and a suitable chromagen. Total hemoglobin is determined separately by conversion of all

hemoglobin derivatives of the samples into hematin using an alkaline method as described in Zander *et al* (1984). The A1c concentration is expressed as a concentration ratio of glycated hemoglobin to total hemoglobin.

Intended Use of the Device:

HbA1C Enzymatic Assay is intended for the *in vitro* quantitative determination of stable HbA1c (glycated hemoglobin A1c; A1c) in human whole blood samples. Measurement of hemoglobin A1C is a valuable indicator for long-term diabetic control.

HbA1C Enzymatic Assay Kit contains an A1C calibrator and a THb calibrator. The calibrators are design to be used with the assay for the quantitative determination of HbA1C in blood.

HbA1C Enzymatic Assay has controls design to be used with the assay for the quantitative determination of HbA1C in blood.

Performance Characteristics

Diazyme's HbA1C Enzymatic Assay is a two reagents based kinetic assay system. The assay offers excellent precision as shown in the table below:

	5.3% A1c	12% A1c
Intra-Assay Precision	CV%= 3.5%	CV%= 1.6%
Inter-Assay Precision	CV%= 5.0%	CV%= 7.2%

Diazyme's HbA1C Enzymatic Assay has a good correlation with Tosoh's method with a correlation coefficient of 0.92. We have conducted interference study by spiking the substances to be tested to the pooled human sera and found little interference at the indicated concentrations:

Interference	Concentration
Triglyceride	2000 mg/dl
Bilirubin	10 mg/dl
Ascorbic Acid	4 mg/dl
Uric Acid	5 mg/dl
Glucose	2400 mg/dl

Conclusion: Comparison analysis presented in the 510K submission for this device in the comparison section, together with linearity, precision and interference study presented demonstrated that the Diazyme's HbA1C Enzymatic Assay has excellent accuracy and is safe and effective. There is no significant deviation between the results obtained by Diazyme's HbA1C Enzymatic Assay and legally marketed predicate when testing clinical patient samples.

Therefore, Diazyme's HbA1C Enzymatic Assay is substantially similar to the commercially available products to measure HbA1c (glycated hemoglobin A1c; A1c) in human whole blood samples.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 28 2005

Mr. Huan Tran
Quality Assurance Manager
Diazyme Laboratories Division
General Atomics
3550 General Atomics Court
San Diego, CA 92121

Re: k050178
Trade/Device Name: HbA1C Enzymatic Assay Kit
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP, JIS; JJX
Dated: June 1, 2005
Received: June 3, 2005

Dear Mr. Tran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050178

Device Name: HbA1C Enzymatic Assay Kit

Indications for Use:

HbA1C Enzymatic Assay is intended for the *in vitro* quantitative determination of stable HbA1c (glycated hemoglobin A1c; A1c) in human whole blood samples. Measurement of hemoglobin A1C is a valuable indicator for long-term diabetic control.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K050178